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| EXAMINER |
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| WOODWARD, CHERIE MICHELLE |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/918,508 | KAKIMOTO ET AL. | |
| | Examiner | Art Unit | |
| | CHERIE M. WOODWARD | 1647 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *18 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-8,20,21 and 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,20,21 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Formal Matters*

1. Applicant's Response and Amendments filed 4/18/2008 are acknowledged and entered. Claims 1-8, 20, 21, and 28 are pending and under examination.

### *Response to Arguments*

2. Applicant's statements in Applicant's "Summary of Telephone Calls of August 29, 2007, October 2, 2007, and October 5, 2007" (Remarks, page 8) are not entirely accurate. Applicant's representative mischaracterizes the examiner's comments regarding claim amendments. The examiner did not state that any particular changes would be "sufficient" or "acceptable". This is evidenced by the interview summary mailed contemporaneously to the aforementioned telephone calls (attached to the Office Action, mailed 10/18/2007). The interview summary stated that "it is not necessary for applicant to provide a separate record of the substance of the interview since the interview did not result in a resolution of all issues." No agreements were reached during any of the aforementioned telephone calls, as evidenced by the non-final Office Action mailed 10/18/2007. The examiner's position as to the claims is specifically set forth in the Office Action mailed 10/18/2007.

### *Claims Objections/Rejections Withdrawn*

3. The rejection of claims 1 and 28 under 35 USC 112, second paragraph, is withdrawn in light of Applicant's amendments.

### *Claim Objections/Rejections Maintained*

### *Claim Rejections - 35 USC § 112, First Paragraph*

### *Scope of Enablement*

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-8 and 28 remain rejected under 35 USC 112, first paragraph, as lacking enablement commensurate in scope with the claims, for the reasons of record and the reasons set forth herein.

Applicant argues that the cancellation of claim 8, subpart (d) and the amendment of claim 8, subpart (h) to recite a Markush group is sufficient to overcome the rejections of record (Remarks, p. 11,

first paragraph). Applicant argues that Ex Parte Kubin stands for the proposition that extensive experimentation required to practice the full scope of the invention may still be routine experimentation (Remarks, p. 11, second paragraph). Applicant also sites MPEP 2164, 2164.01, and 2164.01 in support of the argument that complex experimentation does not render the experimentation undue, that a disclosure of every operable species is not required to support a degree of predictability, and that the absence of working examples will not, by itself, render the invention non-enabled (Remarks, p. 11, second paragraph). Applicant argues that it would be within the common technical practice for one of ordinary skill in the art to perform a homology search or alignment to determine the degree of similarity between the disclosed sequences and to surmise from the homology search or alignment the regions of conserved amino acids that are important for function without undue experimentation (Remarks, p. 11, last paragraph, to page 12, first paragraph). With regard to claim 28, Applicant states that the amendments thereto have overcome the rejection (Remarks, p. 12, second paragraph) and that the specification teaches methods for obtaining such a polypeptide (Remarks, p. 12, third paragraph). Applicant's arguments have been fully considered, but they are not persuasive.

Claims 1-8 and 28 encompass a broad genus of "cytokinin receptor genes" which include variants thereof, as evidenced by dependent claim 8 and its subparts, particularly subpart (g) and (h) as amended by the amendments filed 4/18/2008. Using SEQ ID NO: 2 (AHK3) as an example, 235 changes could be made to the 1176 amino acid protein and still be within the claimed 80% homology. Although the structure of cytokinin receptors AHK2, AHK3, and CRE1 are known in the art, there is no teaching in the specification or the art as to which domains or regions of the proteins are required to retain cytokinin receptor function. Applicant's argument that one of skill in the art can merely select a homologous sequence from a database for comparison does not reach the level of analysis needed to determine whether any given substitution, addition, or deletion to the primary, secondary, or tertiary structure of the protein will result in functional changes. Such a determination would require undue experimentation, as one of ordinary skill in the art would have to make enough representative species and test the same for activity without knowing which residues or domains are critical to functionality. Because there is no teaching in the specification or the art as to which domains or regions of the proteins are required to retain cytokinin receptor function, having to make and test the broad genus of structural variants would be highly unpredictable.

Amended claim 8, subsections (g) and (h) (as amended on 4/18/2008) remain of particular concern. Applicant's attempt to amend claim 8 to recite specific species of cytokinin receptors are noted, However, Applicant is encouraged to review the new claim rejection under 35 USC 112, second

paragraph below, for the examiner's comment on this amendment. Applicant did not address the examiner's concerns regarding the receiver regions of the claimed chimeras in amended claim 8, subpart (h). Subpart (h) encompasses cytokinin receptor extracellular regions, transmembrane regions, and histidine kinase regions all derived from the same cytokinin receptor, and receiver regions which are not derived from the same cytokine receptor. However, the specification does not provide any guidance as to where these other receiver regions would come from. Are they to come from different cytokinin receptors? If so, which ones? Are they to be taken from non-cytokinin receptors? If so, which ones? There is insufficient guidance as to the structure of these receiver regions such that the person of ordinary skill in the art would understand their structure. Subsection (h) encompasses a genus of cytokinin receptors comprising amino acid sequences of (a), (b), (c), (d), (e), or (f) with deletion, substitution, or addition of one or a plurality of amino acids. The specification does not teach which deletions, substitutions, or additions of one or a plurality of amino acids wherein the amino acid sequence has 80% or higher identity to the amino acid sequence before the deletion, substitution, or addition of amino acids may be made without affecting the function of the cytokinin receptor.

Applicant's arguments that one of ordinary skill in the art can search a sequence database for homologous proteins and nucleic acids and *ab initio* predict the function of those homologues comprising any addition, substitution or deletion within 80% homology is inaccurate. The art acknowledges that function cannot be predicted based solely on structural similarity to a protein found in the sequence databases. For example, Skolnick et al. (2000, Trends in Biotech. 18:34-39) state that knowing the protein structure by itself is insufficient to annotate a number of functional classes, and is also insufficient for annotating the specific details of protein function (see Box 2, p. 36). Similarly, Bork (2000, Genome Research 10:398-400) states that the error rate of functional annotations in the sequence database is considerable, making it even more difficult to infer correct function from a structural comparison of a new sequence with a sequence database (see especially p. 399). Such concerns are also echoed by Doerks et al. (1998, Trends in Genetics 14:248-250) who state that (1) functional information is only partially annotated in the database, ignoring multi functionality, resulting in underpredictions of functionality of a new protein and (2) overpredictions of functionality occur because structural similarity often does not necessarily coincide with functional similarity. Smith et al. (1997, Nature Biotechnology 15:1222-1223) remark that there are numerous cases in which proteins having very different functions share structural similarity due to evolution from a common ancestral gene. Brenner (1999, Trends in Genetics 15:132-133) argues that accurate inference of function from homology must be a difficult problem since, assuming there are only about 1000 major gene superfamilies in nature, then most homologues must have

different molecular and cellular functions. Finally, Bork et al. (1996, Trends in Genetics 12:425-427) add that the software robots that assign functions to new proteins often assign a function to a whole new protein based on structural similarity of a small domain of the new protein to a small domain of a known protein. Such questionable interpretations are written into the sequence database and are then considered facts.

Additionally, the assertion that the disclosed 80% homologues have biological activities similar to known AHK2, AHK3 and CRE1 cytokinin receptors cannot be accepted in the absence of supporting evidence, because the relevant literature reports examples of polypeptide families wherein individual members have distinct, and sometimes even opposite, biological activities. For example, Tischer et al. (U.S. Patent 5,194,596) establishes that VEGF (a member of the PDGF, or platelet-derived growth factor, family) is mitogenic for vascular endothelial cells but not for vascular smooth muscle cells, which is opposite to the mitogenic activity of naturally occurring PDGF which is mitogenic for vascular smooth muscle cells but not for vascular endothelial cells (column 2, line 46 to column 3, line 2). The differences between PDGF and VEGF are also seen *in vivo*, wherein endothelial-pericyte associations in the eye are disrupted by intraocular administration of PDGF but accelerated by intraocular administration of VEGF (Benjamin et al., 1998, Development 125:1591-1598; see Abstract and pp. 1594-1596). In the transforming growth factor (TGF) family, Vukicevic et al. (1996, PNAS USA 93:9021-9026) disclose that OP-1, a member of the TGF-β family of proteins, has the ability to induce metanephrogenesis, whereas closely related TGF-β family members BMP-2 and TGF-β1 had no effect on metanephrogenesis under identical conditions (p. 9023, paragraph bridging columns 1-2). See also Massague, who reviews other members of the TGF-β family (1987, Cell 49:437-8, esp. p. 438, column 1, second full paragraph to the end). Similarly, PTH and PTHrP are two structurally closely related proteins which can have opposite effects on bone resorption (Pilbeam et al., 1993, Bone 14:717-720; see p. 717, second paragraph of Introduction). Finally, Kopchick et al. (U.S. Patent 5,350,836) disclose several antagonists of vertebrate growth hormone that differ from naturally occurring growth hormone by a single amino acid (column 2, lines 37-48).

With regard to claim 28, Applicant did not amend the phrase "a polynucleotide comprising the nucleotide sequence" in claim 28, as explained in the Office Action of 10/18/2007, and this aspect of the claim renders the claim non-enabled in its full scope. The phrase "a polynucleotide comprising the nucleotide sequence" may refer to a fragment as small as one to five nucleotides in length up to the full length of the recited sequence. The claim, as amended, reads on 5-mers, oligomers, 80-mers, and the full sequence.

Additionally, with regard to claims 28 and claim 8(h) (as amended on 4/18/2008), the sequence listing shows SEQ ID NOs: 1, 3, and 5 to be the nucleic acids and corresponding amino acid sequences for cytokinin receptors AHK2, AHK3, and CRE1, respectively. There is no teaching or guidance in the specification or in the art as to how these cytokinin receptors can be encoded by a fragment of a complementary nucleic acid, which is recited in the amended claim as "wherein said cytokinin receptor is encoded by a polynucleotide that hybridizes…to a polynucleotide comprising the nucleotide sequence selected from the group consisting of SEQ ID NOs: 1, 3, and 5…" Stated another way, if SEQ ID NOs: 1, 3, and 5, recite the nucleic acid structure of the cytokinin receptors AHK2, AHK3, and CRE1, respectively, it is unclear how the complementary nucleic acid structures also encode these cytokinin receptors. There is also no teaching about how "a polynucleotide" (read as comprising as few as one to five base pairs) can encode an entire cytokinin receptor.

Applicant is reminded that broad claims may be rejected merely because they read on a significant number of inoperative species when examiner sets forth reasonable grounds in support of his or her conclusions that the claims may read upon inoperative subject matter and it becomes incumbent upon applicant either to reasonably limit claims to approximate area where operativeness has not been challenged or to rebut examiner's challenge by submission of representative evidence or by persuasive arguments based on known laws of physics and chemistry (see In re Cook and Merigold, 169 USPQ 298 (CCPA 1971)).

Due to the large quantity of experimentation necessary to generate the large number of cytokinin receptor variants and screen same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function, and the unpredictability of the claims which fail to recite sufficient structural limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

### *Claim Rejections - 35 USC § 112, First Paragraph*

### *Written Description*

6. Claims 1-8, 20, 21, and 28 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for the reasons of record and the reasons set forth herein.

Applicant argues that that the Office Action has misapplied the written description and enablement requirements because the Office Action's rationale is inconsistent with the PTO's guidelines for written description and the BPAI's interpretation for written description and enablement (Remarks, p. 13, sixth paragraph, to page 14, third paragraph). Applicant argues that although the instantly claimed sequence homology differs from that in the written description guidelines (80% herein, versus 95% homology in the Guidelines), the sequences of SEQ ID NOs: 1, 3, and 5 are known and "the methods for making variants of such a reference sequence is considered to be conventional in the art" (Remarks p. 14, last paragraph). Applicant's arguments have been fully considered, but they are not persuasive.

*Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see p. 1115) (see also, University of Rochester v. G.D. Searle & Co., 358 F.3d 916, 69 USPQ2d 1886, 1891 (Fed. Cir. 2004). *Vas-Cath Inc. V. Mahurkar*, also states that Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written description inquiry, is whatever is now claimed (see page 1117).

With respect to Applicant's arguments that the Office Action mailed 10/18/2008 is inconsistent with the Written Description Guidelines, Applicant did not point to any particular part of the Written Description Guidelines or any of the Examples thereto. The examiner cannot adequately respond to Applicant's arguments, when Applicant has only set forth generalized averments without citations to any particular part of the Guidelines. Applicant is reminded that "[c]ompliance with the written description requirement is essentially a fact-based inquiry that will 'necessarily vary depending on the nature of the invention claimed" *Vas-Cath Inc. v. Mahurhar*, 935 F.3d at 1563, 19 USPQ2d at 1117. While the Written Description Guidelines and hypothetical Examples in the Synopsis can be helpful in understanding how to apply the relevant law, as it existed in 2001 when the Guidelines were adopted, (although the Examples were recently updated on 4/11/2008), they do not create a rigid test. Even so, Applicant is strongly encouraged to review the Written Description Guidelines at revised Example 11 (especially as Example 11 refers to exemplary claim 2, regarding a claim which has both a structural and a functional requirement) (revisions published 11 April 2008).

With respect to Applicant's citation of *Ex parte Bandman* (BPAI 2005), the examiner has never stated that a description of the complete structure of every species is required. To the contrary, the examiner stated "[w]hile "examples explicitly covering the full scope of the claim language" typically will not be required, a sufficient number of representative species must be included to "demonstrate that

the patentee possessed the full scope of the [claimed] invention." Lizardtech v. Earth Resource Mapping, Inc., 424 F.3d 1336, 1345, 76 USPQ2d 1724, 1732 (Fed. Cir. 2005)" (Office Action of 10/18/2007, page 7, last paragraph to page 8).

With regard to Applicant's arguments that the sequences of SEQ ID NOs: 1, 3, and 5 are known and that "the methods for making variants of such a reference sequence is considered to be conventional in the art," the question of whether one of skill in the art can make and use the claimed invention is an enablement analysis. The instant rejection pertains to written description and whether Applicant or the art has adequately described the invention such that one of ordinary skill in the art would be aware that Applicant was in possession of the invention, as claimed.

As previously stated of record, there are three species of the claimed genus disclosed that is within the scope of the claimed genus, *i.e.* SEQ ID NOs: 2, 4, and 6 (and corresponding nucleic acid sequences SEQ ID NOs: 1, 3, and 5). However, instant claims 1-8, 20, 21, and 28 encompass a genus of cytokinin receptors, including variants and chimeras, that are not otherwise described in the specification. Claim 8, subsections (d), (e), and (f) (as amended 4/18/2008), are drawn to specific regions of SEQ ID NOs: 2 and 4. Claim 8 subsection (g) (as amended on 4/18/2008), is drawn to a chimera-type cytokinin receptor comprising extracellular regions, transmembrane regions and histidine kinase regions, all of which are derived from the same cytokinin receptor selected from the recited group, and receiver regions which are not derived from said same cytokinin receptor. Claim 8 subsection (h) (as amended 4/18/2008) is drawn to a cytokinin receptor comprising the amino acid sequence of (a), (b), (c), (d), (e), or (f) with deletion, substitution, or addition of one or a plurality of amino acids. Claim 28 is drawn to a generic receptor encoded by a polynucleotide that hybridizes to a polynucleotide selected from the group consisting of SEQ ID NOs: 1, 3, and 5, with cytokinin receptor activity. Independent claim 1 encompasses all of the limitations of the dependent claims. Claims 20 and 21 are drawn to generic cytokinin receptors.

Even if a person of ordinary skill in the art could compute sequence 80% sequence homology in a database, the claims require that the cytokinin activity also be present. Structure is not necessarily a reliable indicator of function (see evidentiary references recited in the scope of enablement rejection, above). There is no disclosure in the instant specification or the art relating the similarity of structure to conservation of function. General knowledge in the art includes the knowledge that some amino acid variations are tolerated without losing a protein's tertiary structure. However, conservation of structure is not necessarily a surrogate for conservation of function. In this case there is no disclosed correlation

between structure and function. Accordingly, one of skill in the art would not accept the disclosure that SEQ ID NOs: 2, 4, and 6 were representative of 80% homologous variants having cytokinin activity.

Applicant has not responded to the examiner's rejection regarding receiver regions in claim 8, subsection (h). Subsection (h) (as amended 4/18/2008) encompasses cytokinin receptor extracellular regions, transmembrane regions, and histidine kinase regions all derived from the same cytokinin receptor, and receiver regions which are not derived from the same cytokine receptor. However, the specification does not describe where these other receiver regions would come from. There is no description of whether they would come from another cytokinin receptor, such that their structure or function could be determined.

In the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed genus, which is a cytokinin receptor with 80% homology to SEQ ID NOs: 2, 4, or 6 with cytokinin receptor function. One of skill in the art would not recognize from the disclosure that the applicant was in possession of the claimed genus. Possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features (see, Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 927, 69 USPQ2d 1886, 1895 (Fed. Cir. 2004); accord Ex Parte Kubin, 2007-0819, BPAI 31 May 2007, opinion at p. 16, paragraph 1).

***New Claim Rejections - Necessitated by Amendment***

***Claim Rejections - 35 USC § 112, Second Paragraph***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Subpart (g) has been amended to recite "consisting of the group selected from CRE1, AHK2, AHK3…" However, the claim also recites "comprising" language. The order of the language in the amendment is confusing because of the "comprising" and "consisting of" language in the same claim. It is suggested that Applicant rephrase the language in subpart (g) to recite "...from the same cytokinin receptor selected from the group consisting of AHK2, AHK3, and CRE1, and receiver regions…" This suggested revision clearly indicates that the three recited species are part of a Markush group and the claim language is less confusing. Additionally, Applicant's amendments to claim 8, subpart (h) and claim 28 (filed 4/18/2008)

render the claims confusing. The sequence listing shows SEQ ID NOs: 1, 3, and 5 to be the nucleic acids and corresponding amino acid sequences for cytokinin receptors AHK2, AHK3, and CRE1, respectively. It is unclear and confusing how these cytokinin receptors can be encoded by a fragment of a complementary nucleic acid, which is recited in the amended claim as "wherein said cytokinin receptor is encoded by a polynucleotide that hybridizes…to a polynucleotide comprising the nucleotide sequence selected from the group consisting of SEQ ID NOs: 1, 3, and 5…" Stated another way, if SEQ ID NOs: 1, 3, and 5, recite the nucleic acid structure of the cytokinin receptors AHK2, AHK3, and CRE1, respectively, it is unclear how the complementary nucleic acid structures also encode these cytokinin receptors. It is also unclear how "a polynucleotide" (read as comprising as few as five base pairs) can encode an entire cytokinin receptor. Claim 8, subparts (g) and (h), as written, are unclear and confusing.

***Conclusion***

NO CLAIMS ARE ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cherie M. Woodward whose telephone number is (571) 272-3329. The examiner can normally be reached on Monday - Friday 9:00am-5:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CMW/
AU 1647

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